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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,201	11/01/2001	Claus Bornaes	0220us210	5811

30560 7590 10/05/2004

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EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/004,201	BORNAES ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2002*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **2-5, 6,** and **9-12**, drawn to an interferon β polypeptide comprising the introduced glycosylation site Q49N+A51T, classified in class 530, subclass 399, for example.

II. Claims **2-5, 7,** and **9-12**, drawn to an interferon β polypeptide comprising the introduced glycosylation site F111N+R113T, classified in class 530, subclass 399, for example.

III. Claims **2-5, 8,** and **9-12**, drawn to an interferon β polypeptide comprising a mutation independently selected from C17S, D110F, K19R, K33R, or K45R, classified in class 530, subclass 399, for example.

IV. Claims **15** and **18-21**, drawn to a conjugate comprising interferon β and a sugar moiety, classified in class 530, subclass 402, for example.

V. Claims **16** and **18-21**, drawn to a conjugate comprising interferon β and a polymer molecule, classified in class 530, subclass 402, for example.

VI. Claims **17** and **18-21**, drawn to a conjugate comprising interferon β and a linear or branched polyethylene glycol, classified in class 530, subclass 402, for example.

VII. Claims **22-26**, drawn to a method of preparing a conjugate, classified in class 435, subclass 69.1, for example.

VIII. Claim **30**, drawn to treating a mammal with a to be selected disease/condition (see below), classification dependent upon therapeutic agent structure.

IX. Claim **31**, drawn to treating a mammal with a to be selected disease/condition (see below), classification dependent upon therapeutic agent structure.

X. Claim **32**, drawn to treating a mammal with a to be selected disease/condition (see below), said mammal having circulating antibodies against interferon β 1a and/or 1b, classification dependent upon therapeutic agent structure.

2. Claims **1** and **27-29** link(s) inventions I, II, and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 2-12. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In*

re Ziegler, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Claims **13-14** and **27-29** link(s) inventions I, II, and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 15-21. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The inventions are distinct, each from the other because of the following reasons:

5. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to <u>different</u> products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I, II, III, IV, V, and VI are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

6. The polypeptide of Invention I can be prepared by processes which are materially different from the polypeptides of Invention II and III as well as the conjugates of Inventions IV, V, and VI such as by chemical synthesis or isolation and purification from natural sources.

7. The polypeptide of Invention II can be prepared by processes which are materially different from the polypeptides of Invention I and III as well as the conjugates of Inventions IV, V, and VI such as by chemical synthesis or isolation and purification from natural sources.

8. The polypeptide of Invention III can be prepared by processes which are materially different from the polypeptides of Invention I and II as well as the conjugates of Inventions IV, V, and VI such as by chemical synthesis or isolation and purification from natural sources.

9. Further, the conjugate of Invention IV can be prepared by processes which are materially different from the interferon β polypeptides of Inventions I, II, and III as well as the conjugates of Inventions V and VI such as by chemical synthesis.

10. And conjugate of Invention V can be prepared by processes which are materially different from the interferon β polypeptides of Inventions I, II, and III as well as the conjugates of Inventions IV and VI such as by chemical synthesis.

11. And the conjugate of Invention VI can be prepared by processes which are materially different from the interferon β polypeptides of Inventions I, II, and III as well as the conjugates of Inventions IV and V such as by chemical synthesis.

12. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions VII, VIII, IX, and X are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention VII requires search and consideration of making a conjugate which is not required by any of the other Inventions. Invention VIII requires search and consideration of any one of a disease/condition selected form a non-overlapping Markush group with any of the other Inventions. Invention IX requires search and consideration of any one of a disease/condition selected form a non-overlapping Markush group with any of the other Inventions. Invention X requires search and consideration of mammal having circulating antibodies against interferon β 1a and/or 1b, which is not required by any of the other Inventions.

13. Each of Inventions I, II, and III and VII are related as products and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the interferon β polypeptides each of Inventions I, II, and III can be used as therapeutics, diagnostics, or to identify binding partners (screening assay).

14. Inventions VII and each of Inventions IV, V, and VI are related as process of making and product made. The inventions are distinct if either or both of the following

can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products of Inventions IV, V, and VI can be made through materially different methods such as chemical synthesis.

15. Each of Inventions I, II, III, IV, V, and VI and VIII are related as products and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the interferon β polypeptides each of Inventions I, II, and III as wells as the conjugates of Inventions IV, V, and VI can be used as diagnostics or to identify binding partners (screening assay).

16. Each of Inventions I, II, III, IV, V, and VI and IX are related as products and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the interferon β polypeptides each of Inventions I, II, and III as wells as the conjugates of Inventions IV, V, and VI can be used as diagnostics or to identify binding partners (screening assay).

17. Each of Inventions I, II, III, IV, V, and VI and X are related as products and a process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the interferon β polypeptides each of Inventions I, II, and III as wells as the conjugates of Inventions IV, V, and VI can be used as diagnostics or to identify binding partners (screening assay).

18. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Viral infection

b. Cancers

c. Tumors

d. Tumor angiogenesis

e. Crohn's disease

f. Ulcerative colitis

g. Guillain-Barré syndrome

h. Glioma

i. Idiopathic pulmonary fibrosis

j. Abnormal cell growth

19. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim **30** is generic.

20. If applicant selects Invention VIII, one species from the disease/condition group must be chosen to be fully responsive.

21. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

22. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

23. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

24. This application contains claims directed to the following patentably distinct species of the claimed invention:

k. Benign multiple sclerosis

l. Relapsing remitting multiple sclerosis

m. Primary progressive multiple sclerosis

n. Secondary progressive multiple sclerosis

o. Monosymptomatic multiple sclerosis

p. Hepatitis

q. Herpes infection

25. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim **31** is generic.

26. If applicant selects Invention IX, one species from the disease/condition group must be chosen to be fully responsive.

27. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

28. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

29. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

30. This application contains claims directed to the following patentably distinct species of the claimed invention:

r. Viral infection

s. Cancers

t. Tumors

u. Tumor angiogenesis

v. Crohn's disease

w. Ulcerative colitis

x. Guillain-Barré syndrome

y. Glioma

z. Idiopathic pulmonary fibrosis

aa. Abnormal cell growth

bb. Benign multiple sclerosis

cc. Relapsing remitting multiple sclerosis

dd. Primary progressive multiple sclerosis

ee. Secondary progressive multiple sclerosis

ff. Monosymptomatic multiple sclerosis

gg. Hepatitis

hh. Herpes infection

31. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim **32** is generic.

32. If applicant selects Invention X, one species from the disease/condition group must be chosen to be fully responsive.

33. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

34. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

35. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record

showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

36. The Examiner has required restriction between product and method claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn method claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Method claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

37. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and method claims may be maintained. Withdrawn method claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re*

Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the method claims should be amended during prosecution either to maintain dependency on the method claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

38. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

39. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

40. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

41. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS10/04

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